



**Coming Soon?
Regulated Psychedelics
for Mental Health &
What You Need to Know**

Michael Coupland, RPsych
August 16, 2023

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Michael Coupland, RPsych

- Psychologist treating first responders since 1979
- Developer of the COPE with Trauma and COPE with Pain work injury recovery programs delivered across the USA
- Implemented the PTSD first responder work comp programs for FL, GA, CA state and county first responders
- Noted the 'naturalistic' use of psychedelics by first responders who were not recovering with usual and customary care
- Post retirement, undertook training in psychedelic medicine and participated in clinical trials and Health Canada exceptions work

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**Stella: Combining Biological & Psychological Treatment
Responsible Innovation Changing the Treatment for Mental Health**

Stella's team of board-certified physicians, advanced practice providers, psychologists provide comprehensive care treating biological and psychological conditions across 35+ locations in the USA, Israel and Australia

Stella's Advanced Ganglion Block

Dual Sympathetic Reset
Treatment to alleviate PTSD symptoms by reducing amygdala ("fear center") overactivity. The procedure first alleviates the brain from the continuous start of fight or flight.

Injection of FDA-approved local anesthetic in the neck.

Effective treatment on a wide range of symptoms and conditions including but not limited to:

- PTSD/PTSS
- Anxiety & Panic attacks
- Intrusive Memories
- Memory Loss
- Depression
- Irritability
- Isolation & Avoidance

concomitantly:

- Reduced Self-Harm
- Disrupted Sleep & Nightmares
- Numbness, Irritability
- Sexual Dysfunctions
- Hypersensitivity

Ketamine Protocol by Stella

Medically Guided Experience & APP Integration Sessions

Stella's Ketamine Treatment Sessions are guided by our responsible innovation approach. Patients are directly medically monitored during their treatments for controlled and monitored dosing and care and our protocol includes Stella Integration Sessions following each infusion.

Treatment provides pain relief in chronic sufferers, relieves anxiety and can act as an effective antidepressant.

Includes an advanced Stella blend of:

- ECG-monitored
- Minors and Anest
- Blind
- Magnesium
- Oxygen
- VAC
- Vitamin C

SOF (Special Operations Forces) Protocol

Award winning multi-modality protocol

For those at high risk of traumatic brain injury (TBI) and PTSD, treatment combines Ketamine Infusions, Stella Integration Sessions and OSR SDB for a synergistic effect.

Trauma-Informed Talk Therapy Curriculum

Dual Sympathetic Reset Therapy Curriculum with APP

Stella and All Points North's curriculum that supports long-term outcomes for clients who receive biological Dual Sympathetic Reset (DSR) treatment as the first step in care.

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What I will Cover Today

- The current landscape of psychedelics available as mental health treatments.
 - Ketamine-assisted psychotherapy is being used as a legal off-label medication, for treatment-resistant mental health conditions
 - Status of Registered Psychedelics Studies in the American Drug Trial Registry
 - Jurisdictional regulatory updates on psychedelics for medical use
- A brief overview of the history, the neurobiology of psychedelics, conditions treated and why they appear to be effective
- Psychedelics Effect on Work Ability
- Psychedelic Treatment Protocol
- Insurance and benefits coverage issues
 - Example cost of treatment via CPT codes
- Lessons learned over the cannabis movement and why employers and payors can benefit from staying educated and up to date



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What is on the horizon:

Psychedelics

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Psychedelic Drugs “empathogens”, “psychotomimetic”, “entheogen”)

1. Serotonergic psychedelics (agonize receptor) - 1
2. Empathogens/Entactogens (release serotonin) - 2
3. Dissociative NMDA receptor antagonists - 3
4. Cannabinoids (CB1 receptor agonists) - 4
5. Others - 5



- LSD (Lysergic acid diethylamide) - 1**
- Designed in lab, hallucinations occur, effect last up to 12 hours.
 - Does not appear to be addictive.
 - Model psychedelic for these therapeutic developments Tens of thousands of patients were
 - treated in the 1950s and 1960s, predominantly in the psychotherapy setting.
 - 10% of people in US have tried it at some point.



- DMT - NN - Dimethyltryptamine - 1 (Ayahuasca)**
- Occurs naturally in humans, plants, animals.
 - Used historically in Amazon for spiritual purposes.
 - Rapid onset, rapid effects.



- Psilocybin - 1**
- Occurs naturally in mushrooms (>200 types).
 - Converts to psilocin in the body, lasts 6+hrs. Used historically for healing/spirituality.
 - Being extensively studied today.



- MDMA - 2**
- 3,4-methylenedioxymethamphetamine
 - Commonly known as ecstasy and involved in rave culture.
 - Effects last up to 8 hours
 - Has completed second Phase 3 clinical trial for PTSD
 - Is expected to go to FDA for approval in 2023



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Psychedelic Drugs “empathogens”, “psychotomimetic”, “entheogen”) cont.

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tetrahydrocannabinol

Tetrahydrocannabinol (THC) - 4

- Found in the cannabis plant.
- Binds to receptors in brain and immune system. Regulates homeostasis in the body.
- Is being used in medically prescribed dosage for anxiety, PTSD, depression, insomnia
- Psychedelic dosage is being explored

Lophophora williamsii

Peyote 1.Mescaline

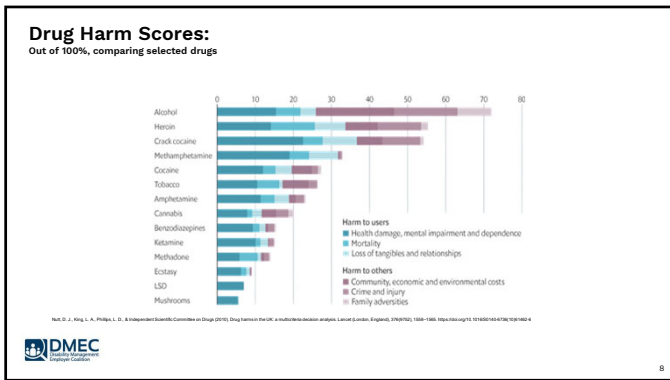
- Found in cactus most commonly mescaline.
- Known spiritually as the “divine messenger”.
- Used by indigenous communities worldwide.

Ketamine
 $C_{15}H_{17}NO$

Ketamine

- Synthesized in 1960s.
- Used as buddy drug in war time.
- Dissociative effects. High dosages used as anesthesia.
- Being safely used for depression today.
- Effects last 45min - 1hr.
- Over 200 clinics in the USA offering this treatment

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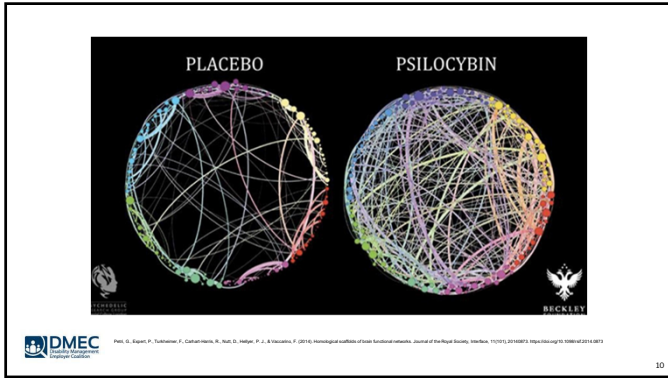
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Neuroplasticity:

An umbrella term that refers to the brain's ability to modify, change, and adapt both structure and function throughout life and in response to experience.

Psychedelic drugs can take advantage of this feature of the brain and open a window of aggressive neuroplasticity.

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The Default Mode Network

- Network of brain regions that are active when the brain is at rest
- Includes various sections of the brain
- Supports mind wandering or rumination
- Communicated with language and speech areas; may give rise to internal monologue
- Psychedelic experiences loosen this network
- A loosened network is more high entropy: infant consciousness, creative/divergent thinking VS low entropy state: addiction, OCD, rigid thinking depression

Two brain scan images showing the Default Mode Network. The left image is a sagittal view and the right is an axial view. Both show several red-colored regions of activity within the brain's network.

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Measuring a Psychedelic Experience (through a non-clinical lens)

MEQ30 (Mystical Experience Questionnaire)

Factor 1: Mystical

- Freedom from the limitations of your personal self and feeling a unity or bond with what was felt to be greater than your personal self.
- Experience of pure being and pure awareness (beyond the world of sense impressions).
- Experience of oneness in relation to an "inner world" within.
- Experience of the fusion of your personal self into a larger whole.
- Experience of unity with ultimate reality.
- Feeling that you experienced eternity or infinity.
- Experience of oneness or unity with objects and/or persons perceived in your surroundings.
- Experience of the insight that "all is One".
- Awareness of the life or living presence in all things.
- Gain of insightful knowledge experienced at an intuitive level.
- Certainty of encounter with ultimate reality (in the sense of being able to "know" and "see" what is really real at some point during your experience).
- You are convinced now, as you look back on your experience, that in it you encountered ultimate reality (i.e., that you "knew" and "saw" what was really real).
- Sense of being at a spiritual height.
- Sense of reverence.
- Feeling that you experienced something profoundly sacred and holy.

Factor 2: Positive Mood

- Experience of amazement.
- Feelings of tenderness and gentleness.
- Feelings of peace and tranquility.
- Experience of ecstasy.
- Sense of awe or awelessness.

Factor 3: Transcendence of Time and Space

- Loss of your usual sense of time.
- Loss of your usual sense of space.
- Loss of usual awareness of where you were.
- Sense of being "outside of" time, beyond past and future.
- Being in a realm with no space boundaries.
- Experience of timelessness.

Factor 4: Ineffability

- Sense that the experience cannot be described adequately in words.
- Feeling that you could not do justice to your experience by describing it in words.
- Feeling that it would be difficult to communicate your own experience to others who have not had similar experiences.

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Psychedelic Treatment Outcomes

MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study

Journal: M. Mitschke^{1,2}, Michael Engemeier^{1,2}, J. Peter Dillig¹
Nature Medicine (2021) | Cite this article
DOI: [10.1038/s41591-021-10191-9](https://doi.org/10.1038/s41591-021-10191-9)

After their three sessions, 67% of participants in the MDMA for PTSD group no longer qualified for a PTSD diagnosis, MAPS said, with 88% having a "clinically meaningful reduction in symptoms."




November 4, 2020

Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder

A Randomized Clinical Trial

David C. Dorey, PhD¹, Frederick S. Barrett, PhD², Dennis C. Hoyle, PhD^{1,3}
7 Author Affiliations | Article Information
DOI: [10.1001/psychiatry.2021.0085](https://doi.org/10.1001/psychiatry.2021.0085)


NNT ~2-4 (various studies) 50%-60% remissions after completion

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Paradigm Shift in Mental Health

Current Psychopharmacological Approach	New Approach
<ul style="list-style-type: none"> Daily use of SSRIs and other psychotropic medications that blunt emotional response Passive 'wait and see' for results Takes weeks to appreciate benefits, slightly better than placebo Often prescribed without psychotherapy support Despite access to many medications mental health issues rising for decades Focuses on symptom reduction 	<ul style="list-style-type: none"> Legal psychedelic therapies (Ketamine for now) Stellate Ganglion Block biological treatment Rapid patient response (within days) with established treatment protocols One-six dosing(s) and psychotherapy integration sessions Neuroplastic and biological changes Emotional breakthroughs and sustained transformational experiences, where patients are empowered to enact their own lasting, meaningful changes




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There is a robust level of clinical development in psychedelic medicine: Current Psychedelic Clinical Trials

Condition or Disease	# of trials	% of trials
Healthy* safety profile	35	33.3%
Substance use disorder	14	13.3%
PTSD	9	8.6%
Depression	8	7.6%
Pain	8	7.6%
Alcohol	5	4.8%
Cancer	5	4.8%
Multiple Conditions	4	3.8%
Marijuana/cannabis	4	3.8%
Headache disorder	4	3.8%
Psychosis/schizophrenia	3	2.9%
Opioids	3	2.9%
Chronic pain	3	2.9%
OCD	2	1.9%

One Clinical Trial Condition or disease

- Cocaine addiction
- Nicotine addiction
- Anorexia nervosa
- Anxiety disorders
- Autism spectrum disorder
- Bipolar disorder
- Hepatic impairment
- HIV
- Obstructive sleep apnea
- Tourette syndrome
- Trichotillomania
- Depression, Anxiety, PTSD
- Depression, depressive symptoms, Alzheimer's disease, mild cognitive impairment
- Distress/grief, depression
- Tourette syndrome, tic disorder
- Migraine
- Post-traumatic headache
- Alzheimer's disease
- Parkinson's disease
- Post-operative pain
- Post-traumatic pain
- Neuropathic low back pain
- Inflammatory bowel disease
- Sickle cell disease



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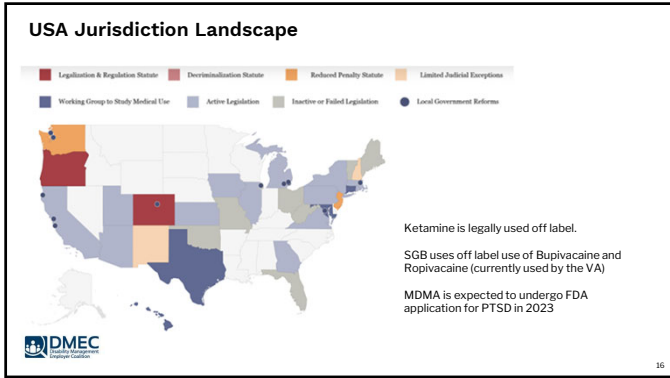
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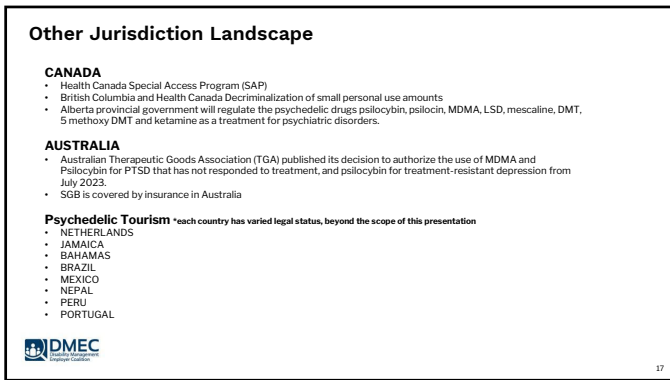
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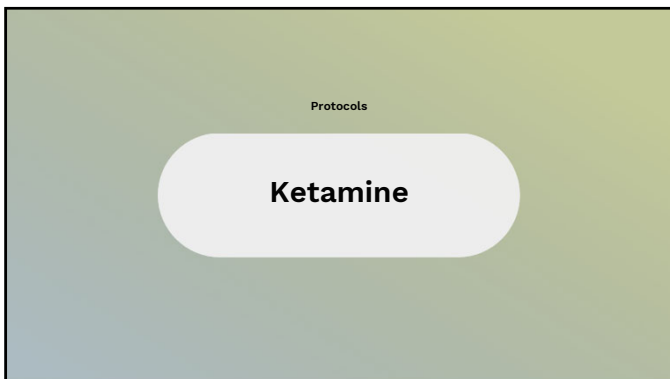
Michael Coupland, 7/6/2023



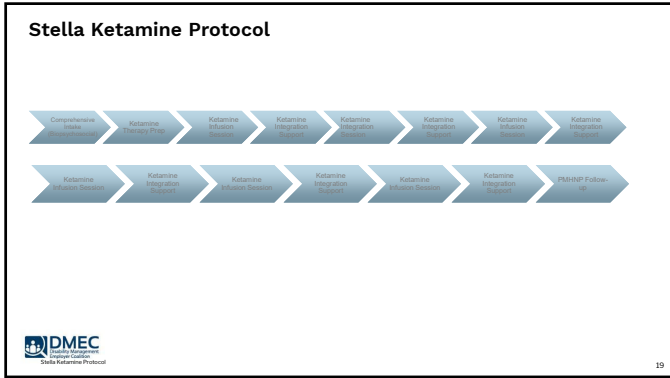
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Mindset and Therapeutic Component

Preparation

- Information about psychedelic treatments and the ways they help us heal
- Information about what to expect during your Ketamine infusion session at a Stella clinic
- Information to help each patient prepare - physically, mentally and emotionally - for their healing journey, including setting a specific intention for their infusion session

Examples:
"I want to feel calm and at peace in my body."
"I want to experience more joy, and less frustration."

- And information to help each patient understand the care and follow up they'll receive after each Ketamine infusion session

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Mindset and Therapeutic Component

Integration

- Critical process of making meaning of the content that emerges during psychedelic medicine sessions
- Assessment of somatic, cognitive, emotional and relational experiences
- Supported by licensed mental health experts
- Vital component that helps create long-lasting changes as a result of brief courses of treatment

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Slide 20

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Slide 21

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Doc Springer, 7/6/2023
- 2 Ok
Michael Coupland, 7/6/2023

Psychedelics and Work Ability

A pilot retrospective analysis, Coupland 2023

Introduction:

This study compares the effectiveness of Ketamine Assisted Psychotherapy to concurrently impact work abilities correlated to the impact on depression, anxiety, and PTSD symptoms

Methods:

Pre and post treatment depression symptoms (PHQ9), anxiety symptoms (GAD7) and PTSD (PCL6) symptoms were retrospectively assessed in a pilot data analysis of 30 patients who volunteered to be interviewed regarding pre and post treatment **work ability index (WAI)** and work status.

Results:

All measures show pre vs post treatment statistically significant clinical improvement via Cohen's d statistical analysis and previous research on minimal clinically important change (MCIC)

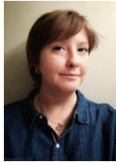


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Patient Experiences and Testimonials

"After years of feeling stuck, I finally feel like I have all of the pieces I need to improve my mental health. I'm back into fitness and more open to exploring new things. I've learned a lot about intention setting and integration, and I've gotten back into reading for the first time in years."

- **Byron**, Former Canadian Armed Forces Infantryman



"My mind was opened to the full experience of being human. I had been blocking myself off from some things because I was afraid of the emotions that were associated with them. Ketamine allowed me to explore those dead zones when I did the treatments in October 2021, and I've gotten even better since then. These treatments honestly set me up for success over time."

- **Katie**, Market Researcher

"I think the biggest breakthrough and most impactful thing is the integration 24 hours later with your psychotherapist while you're still in the residual effect of the ketamine, which actually gets you to look at your trauma while you're dissociated from it... still go through good days and bad days, but now I just have more tools in my toolbox to be able to cope."

- **Bruno**, Former Military & Performance Coach



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Psychedelics, Insurance and Benefits

The pending medicalization of psychedelic medicine protocols

- Legalization of psychedelics is, as of now, a state-level effort in conflict with federal law.
- Legislative changes that take place at the state level do not change the fact that these substances are federally illegal.
- FDA approvals will change this and then state regulatory frameworks on medical use will apply
- Time based CPT codes currently exist for many components of the psychedelic treatment protocol EXCEPT for prolonged guided experience
- AMA and Medicare will be involved in new code development

CPT	CPT Description	Psychiatric Protocol Description	Units	Relative Medicare Reimbursement	Example Commercial Insurance Medicare Reimbursement
	Initial assessment for appropriate use with risk assessment			14	\$225
90791	Psychedelic facilitated with medical services	High Contact	1	\$200.00	\$215.17
90792	Psychedelic facilitated without medical services	Therapy table	1	\$175.00	\$185.00
Preparation					
90807	Psychedelic 501 insurance	Preparation	1	\$207.07	\$205.00
Treatment Session					
90807	Established patient office or other supervised and complex	Observance and preparation on day of treatment	1	\$179.00	\$185.00
90808	Clinical CPT extended monitoring	Guided experience up to 60 min	1	\$18.00	\$18.00
90809	Clinical CPT extended monitoring	Additional each 30 min (12 units available for total 360 min session)	12	\$200.00	\$240.00
Integration					
90807	Psychedelic 501 insurance	Integration	1	\$202.00	\$207.00
Total				\$985.00	\$1,070.07
Each Additional Treatment Session				\$865.07	\$912.00
Cost of 501 & 502e 90808 protocol				\$1,514.00	\$1,490.07



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Regulatory and Policy Prospective Road Map

Issues:

Employers will be addressing paying for psychedelic medicine via health plan, via employee use of their HSA, via work comp benefits.

Employers will be addressing disability peer review of psychedelic medicine recommendations by treating providers.

Employer Occupational health medical surveillance reporting of psychedelic medicine use, especially in safety-sensitive jobs

1. **Step One:** Employers will need to address these issues in States that legalize and regulate psychedelic medicine before it is FDA-approved for therapeutic use

1. **Step Two:** Employers will need to address these issues when FDA approves for therapeutic use:

- a) AMA will need to develop some new billing codes to reimburse for the exploration stage. The assessment, preparation and integration stages are covered adequately with E&M codes
- b) Treatment guideline organizations, health plans, disability plans and work comp will need to develop or adopt clinical and UR guidelines.



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We are entering an exciting, and virtually uncharted territory exploring responsible innovation with the use of new healing modalities including psychedelics

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